

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application of : Drechsel, K. et al ) Art Unit: 1616  
U.S. Appln. No. : To Be Accorded ) Examiner: Mina HAGHIGHATIAN  
Confirmation No. : To Be Accorded  
U.S. Filing Date : 12/15/2003  
Title of Invention : Inhalable Formulation Of A Solution Containing A Tiotropium Salt  
Attny. Docket No.: 1/1156-1-C1

Commissioner for Patents  
P. O. Box 1450  
Alexandria, VA 22313-1450

December 15, 2003

**TRANSMITTAL LETTER FOR INFORMATION DISCLOSURE STATEMENT**

Sir:

Transmitted herewith concerning the subject application is an Information Disclosure Statement (Form 1449A/B) under 37 C.F.R. §§1.56 and 1.97, as more specifically described hereinbelow.

☒ 1.97(b). This Statement is being filed: i) within three (3) months of the filing date of a national application other than a continued prosecution application under 33 C.F.R. §1.53 (d); ii) within three (3) months of the date of entry of the national stage as set forth in 37 C.F.R. §1.491 in an international application; iii) before the mailing of a first Office action on the merits; or iv) before the mailing of a first Office action after the filing of a request for continued examination under 37 C.F.R. §1.114.

☐ 1.97(c). This Statement is being filed after the time period specified in 37 C.F.R. §1.97(b), but before the mailing date of: i) a final action under 37 C.F.R. §1.113, ii) a notice of allowance under 37 C.F.R. §1.311, or iii) an action that otherwise closes prosecution in the application. This Statement is being accompanied by:

☐ A statement as specified in 37 C.F.R. §1.97(e) [see below]; or

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No.

02-2955.

☐ 1.97(d). This Statement is being filed after the period specified in 37 C.F.R. §1.97(c) but on or before payment of the issue fee. This Statement is accompanied by a statement as specified in 37 C.F.R. §1.97(e) [see below] and the fee set forth in 37 C.F.R. §1.17(p).

☐ 1.97(e).

☐ Each item of information contained in the instant information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to the filing of the instant information disclosure statement; or

☐ No item of information contained in the instant information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and, to the knowledge of the person signing this certification after making reasonable inquiry, no item of information contained in the instant information disclosure statement was known to any individual designated in 37 C.F.R. §1.56(c) more than three (3) months prior to the filing of the instant information disclosure statement.

☐ The fee set forth in 37 C.F.R. §1.17(p).

☐ The Commissioner is hereby authorized to charge payment of the \$180.00 fee set forth in 37 C.F.R. §1.17(p) to Deposit Account No. 02-2955.

☐ 1.704(d). Each item of information contained in the accompanying information disclosure statement was cited in a communication from a foreign patent office in a counterpart application, which communication was not received by any individual designated in section 1.56(c) more than thirty (30) days prior to the filing of the accompanying information disclosure statement.

☒ The Commissioner is hereby authorized to charge payment of any additional filing fees required under 37 C.F.R. §1.16 and any patent application processing fees under 37 C.F.R. §1.17, or credit any overpayment of same, to Deposit Account No. 02-2955.

Triplicate copies of this form are enclosed.

Respectfully submitted,

A handwritten signature in black ink that reads "Michael P. Morris". The signature is written in a cursive style with a large, stylized 'M' and 'P'.

Michael P. Morris  
Attorney for Applicant(s)  
Reg. No. 34,513

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Date: December 15, 2003

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Sheet 1 of 1

**Complete if Known**

Application Number	To Be Accorded
Filing Date	12/15/2003
First Named Inventor	Karen DRECHSEL
Art Unit	1616
Examiner Name	Mina Haghighatian
Attorney Docket Number	1/1156-1-C1

**U. S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 4,042,700 B1	08/16/1977	Banholzer, R. et al	
		US- 4,608,377 B1	08/26/1986	Banholzer, R. et al	
		US- 4,783,534 B1	11/08/1988	Banholzer, R. et al	
		US- 5,610,163 B1	03/11/1997	Banholzer, R. et al	
		US- 5,654,314 B1	08/05/1997	Banholzer, R. et al	
		US- 5,770,738 B1	06/23/1998	Banholzer, R. et al	
		US- 5,952,505 B1	09/14/1999	Banholzer, R. et al	
		US- 6,486,321 B1	11/26/2002	Banholzer, R. et al	
		US- 6,506,900 B1	01/14/2003	Banholzer, R. et al	
		US- 2002/0137764 A1	09/26/2002	Drechsel, K. et al	
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**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				
		DE 196 53 969 A1	06/25/1998	BI KG		
		DE 196 25 027 A1	01/02/1997	BI KG		
		DE 199 21 693 A1	11/16/2000	BI Pharma KG		
		WO 96/32939 A1	10/24/1996	BI KG		

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Considered

\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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